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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,277	09/25/2001	Ralf M. Luche	200125.434	9940
500	7590	03/12/2004	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 6300 SEATTLE, WA 98104-7092			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 03/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/964,277	<b>Applicant(s)</b> LUCHE ET AL.	
	<b>Examiner</b> MISOOK YU, Ph.D.	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-98 is/are pending in the application.
- 4a) Of the above claim(s) 1-50, 59 and 64-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-55, 57, 58 and 60-63 is/are rejected.
- 7) ☒ Claim(s) 56 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>01/09/02, 08/14/02</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> .           |

Continuation of Attachment(s) 6). Other: Sequence Alignment (total 7 pages).

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of group XV claims 51-58, 60-63 in the Paper filed on 12/08/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

As applicant noted in the Paper filed on 12/08/2003, Groups II, and XV are drawn to polynucleotides. For claim 94 missing in the Restriction Requirement mailed on 09/08/2003, it belongs to Group XXV.

Claims 1-50, 59, 64-98 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the Paper filed on 12/08/2003.

Claims 1-28 are pending and claims 51-58, 50-63 are examined on merits.

### ***Specification***

The disclosure is objected to because it contains at page 50, the last line, an embedded hyperlink and/or other form of browser-executable code. Applicant is requested to go over the entire application if there is any other occurrence of browser-executable code in this application. Applicant is required to all delete the embedded hyperlink and/or other form of browser-executable code(s). See MPEP § 608.01.

### ***Claim Objections***

Claim 55-58 is objected to because of the following informalities: the claim depends on claim 50 that belong to a non-elected invention. Appropriate correction is required.

For the purpose of this Office action, the limitation of claim 50 will be included in examination of claim 55-58. However, this treatment does not relieve applicant the burden of responding to this objection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55, 57, 58, and 60-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are interpreted as drawn to a genus of polynucleotides that are defined by up to 50 % sequence identity with a dephosphorylation activity (claims 55, 57, 58) or to a genus of polynucleotides (claims 60-64) that hybridizes to the complement of SEQ ID NO:20 under the recited conditions.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics

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of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims 55, 57, 58 is a partial structure in the form of a recitation of percent identity up to 50 % with the dephosphorylation activity. There is not even identification of any particular portion of the structure that must be conserved in order to retain the dephosphorylation activity. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. As for claims 60-63, the claims do not have any activity associated with for claimed genus of the hybridizing polynucleotides. Accordingly, in the absence distinguishing identifying functional characteristics the specification does not provide adequate written description of the claimed genus of the hybridizing polynucleotides

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, given that the specification has only described SEQ ID NO: 20. Therefore, only isolated polynucleotides comprising SEQ ID NO:20

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encoding the amino acid sequence set forth in SEQ ID NO: 21, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is separable from its enablement provision (see page 1115).

A definition by function alone “does not suffice, to sufficiently describe a coding sequence “because it is only an indication of what the gene does, rather than what it is.” *Eli Lilly*, 119 F.

Claims 51-58, and 60-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:20 encoding for the full-length protein SEQ ID NO21, does not reasonably provide enablement for any polynucleotide encoding a fragment of said protein or a mutant of said protein . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification at page 16 discloses that instant SEQ ID NO:20 encodes a 517 amino acid MAP-kinase phosphatase (instant SEQ ID NO:21). The specification does not teach how to use a polynucleotide encoding a peptide or protein without a phosphatase activity. Although one can make polynucleotide encoding 10-15 amino acids fragment of instant SEQ ID NO:21 and/or mutant of SEQ ID NO21 using art-known recombinant DNA technology, the specification does not teach how to make nucleotide encoding 10-15 amino acid fragment with a phosphatase activity or a mutant

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with up to 50 % change in the amino acid sequence of instant SEQ ID NO:21 and still retains a phosphatase activity.

It is well known in the art that even slight modifications in a peptide or protein structure and can have significant and unpredictable effects on biological activity. Bowie et al (Science, 1990, 247:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out biological activity and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (col 1, p. 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (col 2, p. 1306). The sensitivity of proteins to alterations of even a single amino acid (including conservative substitutions) in a sequence are exemplified by Burgess et al (J of Cell Bio. 111:2129-2138, 1990) who teach that replacement of a single lysine residue at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein and by Lazar et al (Molecular and Cellular Biology, 1988, 8:1247-1252) who teach that in transforming

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growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or even with conservative glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity and characteristics of a protein.

The specification does not teach any 10-15 fragment of instant SEQ ID NO:21 has a phosphatase activity. The specification does not teach any mutant up to 50 % change in amino acid sequence of instant SEQ ID NO:21 but still retains a phosphatase activity. The specification does not teach the specific structures responsible for a phosphatase activity, nor provide guidance as to what changes in the structure can be made retaining a phosphatase activity.

Considering limited guidance and no working examples in the specification, unpredictability in the art, it is concluded that undue experimentation would be required to practice the full scope of the claimed invention.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 51-55, 57, 58, and 60-63 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat.6,664,089 (effective filing date Mar. 24, 2000).

The claims are drawn to polynucleotides encoding at least 10 or 15 consecutive amino acids of a polypeptide having SEQ ID NO:21 or mutants with maximum variation up to 50 % difference to SEQ ID NO:21, expression vector comprising said polynucleotides, a host cell transformed with said expression vector, and method of producing said polypeptide using said host cell.

US Pat.6,664,089 teaches (note columns 83-95 and claims 1-6) SEQ ID NO:1 that is 88.5 % identical to instant SEQ ID NO:20, 94.4 % identical to a polynucleotide encoding instant SEQ ID NO:21. The patent also teaches SEQ ID NO:3 that is 94.4 % identical to a polynucleotide encoding instant SEQ ID NO:21. Note the sequence alignment (total 7 pages). US Pat.6,664,089 also teaches expression vector, host cell, and method of producing protein at abstract, columns 81-84 (see Examples 3 and 4).

Thus, the patent anticipates instant claims 51-55, 57, 58, and 60-63.

#### ***Allowable Subject Matter***

Claim 56 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-


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272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne C Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.  
Examiner  
Art Unit 1642

  
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